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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,542	12/11/2003	Stephen C. Wardlaw	5169-0011-1-1	7739
50811	7590 08/10/2006 EXAMINER		INER	
•	ETZ & KOSAKOWS	BHAT, ADITYA S		
1500 MAIN ST. SUITE 912 SPRINGFIELD, MA 01115			ART UNIT	PAPER NUMBER
			2863	
			DATE MAILED: 08/10/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/733,542	WARDLAW ET AL.			
Office Action Summary	Examiner	Art Unit			
	Aditya S. Bhat	2863			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION (6(a). In no event, however, may a reply be time rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	I.  lely filed  the mailing date of this communication.  O (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>02 Ju</u> 2a)⊠ This action is <b>FINAL</b> . 2b)□ This     3)□ Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro				
Disposition of Claims					
<ul> <li>4)  Claim(s) 1-3,5,8-10,14 and 19-24 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-3,5,8-10,14 and 19-24 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9) ☐ The specification is objected to by the Examiner 10) ☑ The drawing(s) filed on 11 December 2003 is/an Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction 11) ☐ The oath or declaration is objected to by the Ex	re: a)⊠ accepted or b)⊡ object drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/14/05	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 8-10, 14 and 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Okuno et al. (USPN 6,629,060)

With regards to claim 1, Okuno et al. (USPN 6,629,060) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument; (Col. 4, lines 8-10)

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes characteristic values for the specimens; (Col. 4, lines 8-10)

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data; (Col. 4 lines 10-17),

performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine functional status of the analytical instrument; (col. 4, liens 8-23) and

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providing notice to an operator regarding the functional status of the analytical instrument. (Col. 4, lines 21-23).

With regards to claim 19, Okuno et al. (USPN 6,629,060) teaches a method for providing quality control in an analytical instrument, said method comprising the steps of:

sending one or more quality control specimens to a operator of the analytical instrument (Col. 4, lines 8-10)

directly or indirectly communicating control data to the analytical instrument, wherein the control data includes acceptable operating standards (Col. 4, lines 8-10) analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data (Col. 4 lines 10-17);

performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine functional status of the analytical instrument; (col. 4, liens 8-23) and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 4, lines 21-23).

With regards to claim 20, Okuno et al. (USPN 6,629,060) teaches a quality control system for analytical instruments, said system comprising:

one or more quality control specimens, each having one or more predetermined characteristic values and an identifier that can identify the quality control specimen (Col.3 lines 41-45);

an analytical instrument, having an analyzer for analyzing the one or more quality control specimens and thereby create instrument analysis data that includes one or more sensed characteristic values (Col. 4 lines 10-17) and

means for notifying an operator regarding the functional status of the analytical instrument (Col. 4, lines 21-23).

With regards to claim 24, Okuno et al. (USPN 6,629,060) teaches method for providing quality control in an analytical instrument, said method comprising the steps of:

providing one or more quality control specimens and control data that includes characteristic values for the one or more quality control specimens, to an operator of the analytical instrument; (Col. 4, lines 8-10)

analyzing at least one of the one or more quality control specimens and thereby creating instrument analysis data (Col. 4 lines1-15), and

providing notice to the operator regarding the functional status of the analytical instrument (Col. 3, lines 10-17).

With regards to claim 2, Okuno et al. (USPN 6,629,060) teaches the evaluation being performed without operator input (Col. 4, lines 7-15).

With regards to claim 3, Okuno et al. (USPN 6,629,060) teaches the evaluation is performed using routines preprogrammed within the analytical instrument (Col. 4, lines 25-27).

With regards to claim 5, Okuno et al. (USPN 6,629,060) teaches the step of performing an evaluation within the analytical instrument of includes a comparison of

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the characteristic values for the one or more quality control specimens and one or more characteristic values created within the instrument analysis data (Col. 4, lines 5-23).

With regards to claim 8 Okuno et al. (USPN 6,629,060) teaches the control data is communicated to the analytical instrument from a remote source via an electronic communications connection (Col. 7, lines 4-10).

With regards to claim 9, Okuno et al. (USPN 6,629,060) teaches communicating to the analytical instrument that the quality control specimen is for quality control purposes (Col. 4, lines 7-10).

With regards to claim 10, Okuno et al. (USPN 6,629,060) teaches communicating to the analytical instrument that the quality control specimen is for quality control purposes is performed without operator input (Col. 4, lines 7-15).

With regards to claim 14, Okuno et al. (USPN 6,629,060) teaches the step of providing a preprogrammed schedule for quality control procedures to analytical instrument (Col. 6, lines 3-5).

With regards to claim 19 Okuno et al. (USPN 6,629,060) teaches the step of providing a standardized utilizing quality control procedures (Col. 8, lines 13-15).

With regards to claim 21, Okuno et al. (USPN 6,629,060) teaches the means for performing an evaluation of the analytical instrument within the analytical instrument does not require input from an operator (Col. 4, lines 7-15).

With regards to claim 22, Okuno et al. (USPN 6,629,060) teaches evaluating the sensed characteristic values of the instrument analysis data using the predetermined characteristic values does not require input from an operator (Col.4, lines 8-15).

With regards to claim 23 Okuno et al. (USPN 6,629,060) teaches a standardized identifier displayed with the system that identifies the system as using quality control procedures (Col. 4, lines 9-10).

## Response to Arguments

Applicant's arguments filed 6/2/06 have been fully considered but they are not persuasive.

Applicant is reminded that during patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

While the meaning of claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allowed. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

In this instance applicant argues that the prior art of record does not teach the evaluation is performed within the analyzer. Examiner agrees that the data is transmitted between the information terminal and the analyzer operator. However, the

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complete quality evaluation process requires data from within the analyzer in order to determine the functional status of the analyzer. Therefore, at least a portion of the evaluation is performed within the analyzer.

#### Conclusion.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditya S. Bhat whose telephone number is 571-272-2270. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Aditya Bhat July 28, 2006

> MICHAEL NGHIEM PRIMARY EXAMINER